

## **THE ROLE OF THE PHARMACEUTICAL INDUSTRY IN NEUROLOGIC EDUCATION: IMPACT ON HOUSE OFFICERS AND MEDICAL STUDENTS**

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**Objectives.** In this presentation I hope to heighten the awareness of the audience to the size of the pharmaceutical industry in terms of revenue, both in the US and abroad, the allocation of spending by the industry for research and development and for promotion of its products, and then discuss the influence the industry exerts upon faculty, house staff, and medical students. I will discuss current ethical guidelines provided by the American Medical Association (AMA), the Pharmaceuticals Research and Manufacturing Association (PhRMA), the Food and Drug Administration (FDA), and the Accreditation Council on Continuing Medical Education (ACCME). After reviewing past and current interactions with pharmaceutical representatives, I will describe new policies in my own institution, and complete the presentation with a personal view of the recent scope of events.

**Perspective.** I give this presentation from the vantage point of a department chair with over 26 years of service in this position. I have observed the benefits and hazards of the pharmaceutical industry in academic health centers, particularly my own center, and will comment on changes implemented locally. Prior to October 1, 2002, pharmaceutical samples provided by the industry and made available to patients were kept in a locked cabinet. After this date the medical center no longer permitted the individual departments to maintain these samples, which I view as a loss to our patients. Prior to July 1, 2003, pharmaceutical representatives provided (i.e., usually brought in) lunch for our resident seminar sessions, which occur three times weekly at noon. The medical center permits this no longer and the total cost to the department to supply this food amounts to approximately \$30,000 annually. Pharmaceutical firms previously provided support for dinner three times annually for faculty and house staff. These are educational events with presentations by two faculty members during the evening. Providing support from the department to replace pharmaceutical industry funding will amount to approximately \$4,500 annually. I view this as another unnecessary loss, and the funds now required to continue providing these services constitute a burden on an academic department with a narrow financial margin.

**Disclosure.** It is important for the audience to know that I have served as a consultant for multiple pharmaceutical companies for many years, all in the context of service on scientific advisory boards, most involving one meeting for a specific issue. I served on the Merck Co. board for a term of 4 years and just completed this term. I have also served on the Food and Drug Administration's Peripheral and Central Nervous System Drugs Advisory Committee from 1983 through 2000, usually in terms of 3 to 4 years, with a year off the committee between assignments, as mandated by law. I served as chair of the committee from 1996 until 2000. The FDA has retained me annually as a consultant during my time off the committee so that the organization can call me into service at any time without delay, and I remain a consultant currently. I have also served on multiple NIH committees, and currently participate in a Clinical Trials Subcommittee of the NINDS Council. I have never and will never directly own stock in pharmaceutical companies owing to my frequent service with the FDA and with various individual companies. This is to ensure that all parties are aware that my advice is wholly based upon scientific issues. In my long tenure as department chair, I have been responsible for the training of many neurologists, and usually five to six adult and one pediatric neurologist completes training annually. I am very pleased that seven of my excellent trainees are now employed by pharmaceutical companies.

**Heightening Awareness.** The pharmaceutical industry has a huge volume of sales, estimated in 2002 at \$145.2 billion in domestic sales and \$51.5 billion in sales abroad for a total of \$196.7 billion (Pharmaceutical Research and Manufacturers of America (PhRMA) ([www.phrma.org](http://www.phrma.org)). The industry spent \$26.4 billion on research and development in the US (constituting 18.2% of domestic sales), \$5.7 billion abroad and \$32.1 billion total (constituting 16.3% of total sales) ([www.phrma.org](http://www.phrma.org)). The costs of promotion of pharmaceuticals for the same year are unavailable, but in 2000 the companies represented by PhRMA spent \$15.7 billion, which included \$7.2 billion of free samples ([www.phrma.org](http://www.phrma.org) and [www.nofreelunch.org](http://www.nofreelunch.org)). According to the website [www.nofreelunch.org](http://www.nofreelunch.org),

research-based pharmaceutical industry spends more on marketing and administration than on research and development. Countering this argument, PhRMA states that pharmaceutical companies spend more on research than on promotion. Clearly these arguments are discrepant, as they are making different comparisons, including marketing and administration in one argument, and including only marketing in the second.

**Promotion.** According to [www.nofreelunch.com](http://www.nofreelunch.com), pharmaceutical companies spent \$2.5 billion on advertising to consumers in 2000. The website states that increases in sales of the 50 most heavily advertised drugs accounted for 47.8% of the \$20.8 billion increase in spending in 2000. Countering this argument, [www.phrma.org](http://www.phrma.org) states that direct-to-consumer advertising helps educate patients about medical conditions and treatment options, encourages dialogue between patients and physicians, prompts patients to discuss illness for the first time with their physicians, and promotes compliance with prescribed treatment. Quite frankly, I view these counter arguments as specious.

**Perspective.** Although the pharmaceutical industry appears to be highly profitable, there are major hurdles facing these companies. The average cost of developing a new drug is \$802 million, and only 3 of 10 marketed drugs produce revenue that matches or exceeds the research and development costs ([www.phrma.org](http://www.phrma.org)). Hence the decision to move a drug into phase I, II and III clinical trials constitutes a huge and expensive decision, and companies can quickly move from highly profitable to highly threatened.

**Influence on Neurologists.** Pharmaceutical manufacturers provide substantial benefits to faculty, house staff and medical students, but these benefits come at a price and with some risk. Faculty members receive payment for service for scientific advisory boards, marketing advisory boards, speakers bureaus, and for participating in research studies. Faculty, house staff, and students benefit from unrestricted education grants, industry-sponsored symposia, patient education materials, and journal sponsorship. Marketing contacts provide free samples, literature, pens, tote bags, books, lunch and dinner for educational meetings, and guest speakers. The risk comes from the conscious and unconscious influence on physician prescribing practices. Multiple studies have shown that pharmaceutical sales representatives (PSRs) influence prescribing habits of physicians through a variety of means that are given in the slide set accompanying this syllabus.

**Reactions to Concerns.** Major concerns about the influence of the pharmaceutical industry's marketing practices upon physicians has led to the development of ethical guidelines from multiple organizations, including the AMA, PhRMA, FDA, and ACCME. Summaries of the details of these guidelines are contained in the slide set that accompanies this syllabus..

**University of Michigan Guidelines.** As indicated above, I wish to present my personal experience with the reaction to aggressive marketing by pharmaceutical representatives. In my institution, now pharmaceutical representatives must register on entry to the facility, receive a badge, and have appointments with specific faculty, house officers, or staff. They are not permitted in patient care areas and are prohibited from conferences involving patient-identifiable information or quality assurance activities. They may not directly bring in food for educational or non-educational activities. They may not present displays or provide detailing to attendees at these conferences.

**A Personal View.** From my perspective, the pharmaceutical industry has been overly aggressive in its detailing practices and direct-to-consumer advertising efforts, and I find the arguments supporting their practices to be less than convincing. Nevertheless, the reactions from medical centers such as my own appear to me to be excessive. In the past quarter century, academic neurology has been transformed by developments in neuroscience, greater understanding of terrible neurological disorders such as Alzheimer's disease, Parkinson's disease and multiple sclerosis, to name a few. This has led to symptomatic and hopefully in some disorders preventative or curative medications. These developments have not come solely from NIH sponsored research (though this accounts for much of the basic scientific understanding of these disorders), but also substantially from the pharmaceutical industry. I view the industry scientists and physicians as colleagues to those of us in academic medicine, and I also view it as my responsibility to assist the industry in any way that my training and experience can benefit the companies. I encourage my own faculty to participate in

pharmaceutical trials, and am pleased that we have many ongoing studies in my own department. Despite all this, we in neurology must be constantly aware of and adhere to sound ethical practices. We must keep in mind that the perception of conflict of interest is tantamount to guilt in having a conflict of interest. Full disclosure has become essential in our professional lives.